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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/572,188	12/12/2006	Stephen Martone	386/05145	2613
44909	7590	07/07/2009		
PRTSI P.O. Box 16446 Arlington, VA 22215			EXAMINER YEH, JENNER	
			ART UNIT 3763	PAPER NUMBER
			MAIL DATE 07/07/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/572,188	Applicant(s) MARTONE, STEPHEN	
	Examiner JENNER YEHL	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 May 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) 13, 14, 24, 26, 35-40 and 48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 15-23, 25, 27-34 and 41-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 March 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/4/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, Species A in the reply filed on May 6, 2009 is acknowledged.
2. Claims 13, 14, 24, 26, 35-40 and 48 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group and Species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on May 6, 2009.

Information Disclosure Statement

3. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 4, 11, 19, 22, 41 and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Bacich et al (US 5749889).

6. RE claims 1, 19 and 41, Bacich et al disclose an invasive probe assembly 100, “surgical access device”, comprising an elongate tube 122, “endoscopic channel”, for insertion into a body cavity (Col 1, lines 5-35), having a central longitudinal axis and a braided tube 118, “guide channel”, comprising a braid (Col 14, lines 39-42), coupled to the elongate tube 122 but not surrounding the elongate tube 122 where the central longitudinal axis of the elongate tube 122 does not coincide with the central axis of the braided tube 118 (Figure 4); and the braided tube 118 is more flexible than the elongate tube 122 (ie. the elongate tube 122 is rigid, Col 12, lines 58-62, and the braided tube 118 is malleable, Col 14, lines 29-33).

7. RE claim 4, Bacich et al disclose elongate tube 122 is a sheath adapted for isolating an elongate probe 110, "endoscope" (Col 11, lines 58-66; Figures 1 and 4).

8. RE claims 11, 22 and 44, Bacich et al disclose the axis of the braided tube 118 located outside elongate tube 122 (Figure 4) and disclose the braided tube is formed of strands of nylon (Col 14, lines 39-42 and lines 50-52).

9. Claims 1, 2, 12, 20 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Boudewijn et al (US 5713851).

10. RE claims 1 and 2, Boudewijn et al disclose a probe assembly comprising an elongate catheter 1 for insertion into a body cavity, having a central longitudinal axis (Figure 1); and a braided tube 5 comprising a braid 12, coupled with the elongate catheter 1, the braided tube 5 having a central longitudinal axis that does not coincide with the central longitudinal axis of the elongate tube (Figure 3; Col 2, lines 37-50).

11. RE claim 12, Boudewijn et al disclose the braided tube 118 has a substantially uniform cross-section (Figure 8).

12. RE claims 20 and 21, Boudewijn et al disclose the braided tube 118 is sufficiently flexible to remain open even when bent at least 90° with a radius of less than 2.5 cm (Figure 8; ie. note the braided tube 118 is sufficiently flexible to bend 180° backward) and the braided tube formed of strands of a relatively rigid material, “metal” (Col 3, lines 3-8).

13. Claims 25, 27-29, 41-45 and 47 are rejected under 35 U.S.C. 102(b) as being anticipated by Engelson et al (US 5312356).

14. RE claim 25, 27, 28, 41, 44 and 45, Engelson et al disclose a probe assembly comprising an elongate tube 34 for insertion into a body cavity (Col 5, lines 10-18 and lines 37-42; Figure 2) and a braided tube 38, “braided sleeve”, comprising a braid, coupled to and along side of the

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elongate tube 34 (Col 7, lines 64-67; Figure 2), wherein the braided tube has an inner surface texture following the braid of the tube and comprises strands which move independently relative to each other and have holes between the strands (Col 7, lines 47-63; ie. braided sleeve 38 is produced from a loose weave) and the braided tube 38 is more flexible than the elongate tube 34 (ie. braided tube 38 is disposed of at the distal end of the catheter, Figure 2, and the distal end is more flexible than the proximal end of elongate tube 34, Col 5, lines 37-42).

15. RE claim 29, Engelson et al disclose the braided tube can apply suction along its length even in a collapsed state, due to spaces between strands forming the braid (ie. braided tube 38 has holes, as discussed above, and is capable of applying suction even in a collapsed state).

16. RE claims 42 and 43, Engelson et al disclose the braided tube 38 is sufficiently flexible to remain open even when bent at least 90° with a radius of less than 2.5 cm (Col 14, lines 35-48; Figures 11 and 12; ie. braided tube 38 is disposed of within catheter 12 and catheter 12 is capable of navigating vessels that are 2-5mm in diameter. Figure 11 demonstrates that the vessel path the catheter navigates curves at least 90°) and formed from a relatively solid material, “metal” (Col 7, lines 47-51).

17. RE claim 47, Engelson et al disclose the braided tube 38 comprising a braid that is coated at its end in a manner which prevents fraying (Col 7, line 64 to Col 8, line 4; ie. braided tube 38 is tightly enclosed in a heat shrink tube which effectively seals the braided tube and prevents fraying).

Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

19. Claims 3, 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bacich et al (US 5749889) in view of Jones (US 5503616).

20. RE claims 16 and 17, Bacich et al disclose all the claimed elements, as discussed above, and disclose that the braided tube 118, "guide channel", may be attached to the access device on an exterior surface with an adhesive (Col 6, lines 33-38). Bacich et al do not disclose an exterior portion of the braided tube coated by an adhesive while a central portion of the braided tube is not coated. Jones teaches an access device with a collapsible guide channel 20, "access channel", affixed to an endoscope 10 (abstract; Figures 5 and 8) where the guide channel 20 is affixed to the endoscope 10 with an adhesive coating 22 applied only at one end of the exterior of the guide channel 20, leaving a central portion of the guide channel 20 uncoated (Col 4, lines 3-18; Figure 1). Jones teaches that having the adhesive coat only a portion of the guide channel allows one to more easily detach the guide channel from the endoscope (Col 4, lines 18-32).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Bacich's guide channel such that it is affixed onto the access

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device with an adhesive coating only on one portion of the guide channel exterior, as taught by Jones, to achieve the predictable result of affixing the guide channel to the access device and for allowing easy release of the guide channel from the access device.

21. RE claim 3, Bacich et al disclose all the claimed elements, as discussed above, but do not specifically disclose the guide channel attached to an endoscope. Jones teaches a guide channel attached to an endoscope (abstract). It would have been obvious to one of ordinary skill in the art to substitute Bacich's sheath for Jones' endoscope to achieve the predictable result of attaching a guide channel to a probe device.

22. Claim 1, 5, 7, 8, 10 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adair (US 5197457) in view of Engelson et al (US 5312356).

23. RE claims 1, 5, 7, 8, 10 and 18, Adair discloses a probe assembly comprising an external sheath S, surrounding an internal sheath 36 that surrounds an elongate tube 40/38 (Figure 4) and a tube C, "catheter", disposed between the external sheath S and the internal sheath 36 (Figure 4). Adair does not disclose the tube C being a braided, flexible tube. Braided tubes are well known in the art and Engelson et al teach a flexible braided catheter (Col 7, lines 47-57; Figure 2) where the braided tube has an inner surface with a texture of the braid, is permeable to liquids and comprises strands which move independently relative to the other (ie. the braid is composed of a loose weave, Col 7, lines 58-63; Figure 3).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute Adair's catheter with a braided catheter, as taught by Engelson

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et al, to achieve the predictable result of supplying a tube flexible enough to navigate through vasculature.

24. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Adair (US 5197457) and Engelson et al (US 5312356) and further in view of Hammerslag et al (US 5203772).

25. RE claim 6, Adair in view of Engelson et al disclose all the claimed elements, as discussed above, but do not disclose the inner surface of the braid comprising an uncoated braid surface. As discussed above, coating a medical device is well known in the art, and it is well known that one can opt not to apply a coat. Further, Hammerslag et al teach that leaving a medical device uncoated is advantageous because it allows for greater flexibility (Col 20, lines 7-11).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to leave Engelson's braided tube uncoated, as taught by Hammerslag, for the purpose of allowing greater flexibility to the braided tube.

26. Claims 1, 7, 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adair (US 5197457) in view of Brown et al (US 5334169).

27. RE claims 1, 7, 8 and 9, Adair discloses all the claimed elements, as discussed above, but does not disclose a flexible braided tube that is more resilient than the internal and external

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sheaths. Brown et al teach a flexible, braided catheter, where the catheter has varying properties of braid reinforcement to effect varying degrees of resiliency (abstract) and Brown et al teach the importance of adequate resiliency for the catheter to properly navigate through human vasculature (Col 1, lines 59-64).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute Adair's catheter with a catheter whose resiliency can be adjusted, as taught by Brown, to achieve the predictable result of providing a flexible catheter and it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the braided tube such that it was of a resiliency greater than Adair's internal or external sheaths, if a greater flexibility in the catheter were desired.

28. Claims 15, 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adair (US 5197457) and Engelson et al (US 5312356) and further in view of Costa (US 4691369).

29. RE claims 15 and 31, Adair in view of Engelson et al and Engelson et al disclose all the claimed elements, as discussed above, and disclose the braided tube stiffened by increasing strand density and/or weave rate (Col 8, lines 25-52; ie. the braided tube has varying flexibility where areas of less flexibility and greater stiffness have greater strand density and weave rate). While Engelson et al do not disclose stiffening the braided tube with a heated die, Engelson's braided tube satisfies the functional limitation of being sufficiently stiffened. Furthermore, Costa

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teaches stiffening a portion of a braided handle by passing the braid through a heated die (Col 1, lines 48-59).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to stiffen Engelson's braided tube through a heated die, as taught by Costa, to achieve the predictable result of stiffening the braided tube.

30. RE claim 30, it would also have been obvious to one of ordinary skill in the art at the time the invention was made to stiffen Engelson's braided tube to any desired stiffness.

31. Claims 1 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adair (US 5197457) in view of Jaraczewski et al (US 4817613).

32. RE claims 1 and 23, Adair discloses all the claimed elements, as discussed above, but does not disclose a braided tube including at least 36 strands. Jaraczewski et al teach a braided catheter where the braid is formed of a range between 8-64 strands (Col 6, line 54 to Col 7, line 2).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute Adair's catheter with a braided catheter comprised of 64 strands, as taught by Jaraczewski, to achieve the predictable result of providing a flexible catheter.

33. Claims 32-34 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Engelson et al (US 5312356) in view of Hammerslag et al (US 5203772).

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34. Re claims 32-34 and 46, Engelson et al disclose all the claimed elements, as discussed above, but do not disclose the braided tube comprising a non-braided coating on the internal surface and on the external surface and do not disclose the braided tube not having a non-braided coating on its internal surface or over most of its length. Coating medical devices is well known in the art, and it is well known that coating is not essential and therefore can be omitted. Hammerslag et al teach a flexible medical device (abstract) and teach that coating the medical device is advantageous because it can provide additional support (Col 19, lines 61-67) and leaving the medical device uncoated is advantageous because it allows for greater flexibility (Col 20, lines 7-11).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Engelson's braided tube based on the desired features of the braided tube, such that it is either coated or uncoated, as taught by Hammerslag, to provide the device with more support or to allow the device greater flexibility.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNER YEH whose telephone number is (571)270-7836. The examiner can normally be reached on Monday-Thursday, 9am-4pm EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on (571)272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. Y./

Examiner, Art Unit 3763

/Nicholas D Lucchesi/

Supervisory Patent Examiner, Art Unit 3763